110TH CONGRESS
2D SESSION

H. R. 7200

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, to establish authorities that provide patients and health care practitioners freedom in the choice of medical treatments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2008

Mr. CANNON introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, to establish authorities that provide patients and health care practitioners freedom in the choice of medical treatments, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Information and Treatment Access Act".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. FINDINGS.

The Congress finds as follows:

(1) The Congress and the American people desire to live healthy lives and foster an effective and

efficient health care system. This system requires timely, accurate, and ever-improving information resources. This will foster maximization of health care outcomes and help health care practitioners and patients partner for more effective results.

(2) The Internet is a unique tool offering access to great volumes of information. Some is accurate and some is not. There has also been extensive government investment in placing medical information on the Internet in many diverse places.

(3) There is a need to consolidate and translate this myriad of information for physicians and consumers, from the listing of clinical trials to the protocols for treatment of various diseases and conditions, as well as the integration of new discoveries and the evaluations of outcomes-based examinations of drugs and devices for conditions other than those for which they are already approved. This will lead to more accurate treatment, fewer medical errors, and more successful outcomes, while also protecting patients, a physician's right to practice medicine, and a patient's right to access the health care the patient desires.

(4) The Food and Drug Administration is uniquely qualified to assist the Nation in fulfilling

this mission to improve health care for the benefit of Americans. The Administration already coordinates the information needs of many government agencies and equivalent regulatory bodies in other countries.

(5) In providing Internet-based forums for obtaining and disseminating health-related information (including information on surgical procedures; complimentary and alternative medicine; dietary supplements and food; and unapproved treatments), the Food and Drug Administration should work closely with educational institutions, schools of medicine, and other appropriate private entities and ensure that the expertise of such entities is appropriately utilized.

TITLE I—FEDERAL INTERNET SITE FOR CONSOLIDATION AND TRANSLATION OF INFORMATION ON DISEASES AND OTHER CONDITIONS

SEC. 101. INTERNET SITE.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall carry out a program whose mission

is, through an Internet site maintained for purposes of the program—

(1) to consolidate and translate health care information that is available to the public from Federal agencies, linking the various health-related Internet sites of such agencies; and

(2) to assist in the translation and reporting of disease or condition protocols for physicians and lay persons.

(b) INFORMATION ON DISEASES AND OTHER CONDITIONS.—The Secretary shall ensure that the Internet site under subsection (a) has capacities that enable a user of the site to enter the name of a disease or other health condition and obtain Internet links appropriate to health care providers, and links appropriate to lay persons, that provide—

(1) an explanation of the health condition; and

(2) information on all available treatment protocols, including—

(A) standard medical practice protocols; and

(B) any clinical trials, and any outcomes-based treatment protocols, that—

(i) are being conducted or supported by the National Institutes of Health;

(ii) are included in the registry and results data bank under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j));

(iii) are being conducted pursuant to the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

(iv) are being conducted pursuant to section 201 of this Act; or

(v) are identified pursuant to section 301 of this Act or pursuant to section 485D(i) of the Public Health Service Act (as added by section 302 of this Act).

(c) FEDERAL DATABASES.—Internet links under subsection (b) shall include the following:

(1) Links that provide information on how to enroll in a clinical trial referred to in subsection (b)(2)(B) and how to be treated under an outcomes-based treatment protocol referred to in such subsection.

(2) Links to Federal electronic databases that are available to the public and provide disease-specific or condition-specific information, including such databases of the National Institutes of Health, the

Centers for Disease Control and Prevention, and the Food and Drug Administration.

(3) A link to the Internet site under section 204(a) (relating to research and treatments carried out pursuant to section 201, and the identity of the health care practitioners involved).

(4) A link to the Internet site under section 301 and the Internet site under section 485D(i) of the Public Health Service Act (as added by section 302 of this Act).

(d) DATE CERTAIN FOR OPERATION OF PROGRAM.—The Internet site under subsection (a) shall be established and ready for use by health care practitioners and lay persons not later than two years after the date of the enactment of this Act.

TITLE II—PATIENT AND PRACTITIONER RIGHTS REGARDING PRACTICE OF MEDICINE

SEC. 201. PATIENT AND PRACTITIONER RIGHTS.

(a) ACCESS TO MEDICAL TREATMENT.—If a patient of a qualifying practitioner chooses to use a drug or device offered by the practitioner as a treatment in the course of his or her professional practice, then notwithstanding the provisions of law specified in subsection (d), the practitioner may in accordance with this title provide the treat-

ment to the patient (and the patient may use the treatment) without regard to whether the drug or device or use thereof is unapproved, including an unapproved drug or device that is made by the practitioner, except as provided in subsection (c).

(b) ADDITIONAL AUTHORITIES.—Notwithstanding the provisions of law specified in subsection (d), but subject to subsection (c), the following applies to a qualifying practitioner in the course of his or her professional practice:

(1) The practitioner may for use in making a drug obtain active ingredients and other substances from sources other than approved drugs, including active ingredients in the form of bulk drugs.

(2) The practitioner may make a new drug through providing instructions to a licensed pharmacist.

(3) A person may supply to the practitioner active ingredients and other substances described in paragraph (1), and may pursuant to paragraph (2) supply such ingredients and substances to a pharmacist.

(4) A person may supply to the practitioner, and the practitioner may receive, an unapproved drug or an unapproved device that is approved for

commercial distribution in any of the following foreign countries: Australia, Canada, France, Germany, Holland, Japan, Sweden, and the United Kingdom.

(5) The practitioner may otherwise introduce a drug or device into interstate commerce; deliver a drug or device for introduction into such commerce; transport a drug or device in such commerce; receive a drug or device in such commerce and deliver the drug or device; and hold a drug or device for sale after shipment of the drug or device in such commerce.

(c) RESTRICTION REGARDING CERTAIN ACTIVE INGREDIENTS.—The authority established in subsections (a) and (b) for a practitioner to make a drug applies only to the use of an active ingredient that—

(1) is an ingredient in an approved drug; or

(2) is an ingredient in an unapproved drug that is approved for commercial distribution in a foreign country specified in subsection (b)(4).

(d) INAPPLICABILITY OF CERTAIN PROVISIONS OF FEDERAL, FOOD, DRUG, AND COSMETIC ACT.—For purposes of subsections (a) and (b), the provisions of law specified in this subsection are section 351 of the Public Health Service Act and the following provisions of the Federal Food, Drug, and Cosmetic Act: sections

501(a)(2)(B) and 501(e) through 501(h); section 502(f)(1); section 505; section 510; section 513; and section 515.

(e) LIMITATION.—Subsections (a) and (b) are subject to sections 202, 203, and 205, and to the definition of the term "drug" established in section 501(3).

SEC. 202. GENERAL SAFEGUARDS.

In the case of an activity under subsection (a) or (b) of section 201 that would in the absence of such subsection be a violation of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, such subsection is effective with respect to a qualifying practitioner only if the following conditions are met:

(1) Engaging in the activity is not a violation of the law of the State in which the activity is carried out.

(2) Before providing an unapproved treatment to a patient, such practitioner provides to the patient a statement in writing in accordance with this paragraph and obtains the signature of the patient on the statement as a declaration that the patient understands the statement and consents to receiving the treatment. The statement is in accordance with this paragraph if the following conditions are met:

(A) The statement provides as follows:

(i) That the approval of the Food and Drug Administration has not been obtained for the drug, device, or use involved, and that such Administration is the Federal agency whose mission is to protect the public health regarding drugs and devices.

(ii) That the practitioner is not authorized to provide the treatment without the clearance of the Secretary under section 203 of this Act, but such clearance provides a lesser standard of protecting the public health than approval by the Food and Drug Administration under the provisions of law otherwise applicable, and such clearance does not authorize the commercial distribution of the treatment.

(B) The statement identifies the health condition for which the treatment is to be provided to the patient, and provides the instructions that the practitioner expects the patient to follow with respect to the treatment.

(C) The statement provides the opinion of the practitioner concerning the risks and benefits of the treatment, including any expected possible side effects, and the statement de-

scribes in general terms the standard of medical care for the health condition involved and explains the manner in which the treatment varies from such standard.

(3) In the case of treatment with an unapproved drug or device made by the practitioner or obtained by the practitioner from another person, the practitioner does not in distributing the drug or device, other than to patients, impose a charge in excess of the amount necessary to recover the costs of making or obtaining, as applicable, the drug or device and providing for transporting the drug or device to other practitioners. This paragraph is subject to the definition of the term "drug" established in section 501(3).

(4) The practitioner is not an employee or agent of any drug or device company, subject to section 401(c)(2).

(5) The practitioner does not, other than in communicating with the patients of the practitioner, advertise or promote the treatment. This paragraph does not with respect to the treatment prohibit publishing articles or letters in scientific or medical journals or publications; speaking or otherwise providing information at scientific conferences or meet-

ings; or any other form of communicating with professionals in scientific or medical fields. Except for the presentation of information to the public pursuant to the program under section 204, this paragraph does with respect to the treatment prohibit providing information in any manner typically used in the course of business to market products or services to the general public.

SEC. 203. FEDERAL REGISTRATION OF UNAPPROVED TREATMENTS; DETERMINATION REGARDING SAFETY.

(a) IN GENERAL.—

(1) SUBMISSION AND CLEARANCE OF REGISTRATION.—In the case of an unapproved treatment whose provision to a patient under section 201(a) would in the absence of such section be a violation of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, section 201(a) is effective with respect to the provision of the treatment to the patient by a qualifying practitioner only if the following conditions are met:

(A) Before providing the treatment to the patient—

(i) such practitioner submitted to the Secretary a registration in accordance with subsection (b); and

(ii) the Secretary made a determination that there is no clear and convincing evidence that the treatment is unsafe.

(B) In the case of a registration that has been cleared, the practitioner submits to the Secretary supplemental notices in accordance with subsection (d).

(2) ADMINISTRATION OF PROGRAM.—This section shall be carried out by the Secretary acting through the Commissioner of Food and Drugs. The Secretary shall establish within the Food and Drug Administration an office or other administrative unit to carry out this section and section 204.

(3) DEFINITIONS.—For purposes of this section:

(A) The term "clear", with respect to a registration under paragraph (1)(A), means a determination described in clause (ii) of such paragraph.

(B) The term "disapprove", with respect to a registration under paragraph (1)(A), means a determination by the Secretary that

the treatment involved fails to meet the standard for clearance under clause (ii) of such paragraph.

(b) REGISTRATION REQUIREMENTS.—For purposes of subsection (a)(1)(A)(i), a registration under such subsection regarding a qualifying practitioner is in accordance with this subsection if the following conditions are met:

(1) The registration provides the identity and business address of such practitioner and such information regarding the medical licensing of the practitioner in the State involved as the Secretary may require.

(2) The registration describes the unapproved treatment involved and states that it is the intent of the practitioner to provide the treatment to one or more patients.

(3) The registration contains all information that, under subparagraphs (B) and (C) of section 202(2), is required to be provided to the patient in the statement under such section.

(4) The registration contains such information regarding such treatment, and is accompanied by such samples and components regarding the treatment, as the Secretary may require.

(5) The registration contains a statement authorizing the Secretary to disclose, for purposes of the program under section 204, the identity of the practitioner, the business address of the practitioner, and information regarding the treatment.

(c) DATE CERTAIN FOR FINAL AGENCY DETERMINATION.—

(1) IN GENERAL.—Not later than 90 days after the date on which a registration under subsection (a) is submitted to the Secretary in accordance with subsection (b), the Secretary shall clear the registration or disapprove clearance of the registration, and shall in writing provide to the qualifying practitioner who submitted the registration a statement of whether or not the registration has been cleared. If clearance was disapproved, the statement shall explain the reasons underlying the disapproval.

(2) DEEMED CLEARANCE.—

(A) NONCOMPLIANCE OF AGENCY REGARDING TIMEFRAME.—If the Secretary does not within the period of time specified in paragraph (1) clear a registration under subsection (a) or disapprove clearance of the registration, the registration is deemed to be cleared.

(B) REGISTRATION OF ADDITIONAL PRACTITIONERS PURSUANT TO PREVIOUSLY CLEARED REGISTRATION.—If a registration submitted by a qualifying practitioner under subsection (a) is cleared, then in the case of the unapproved treatment involved, registrations submitted by other qualifying practitioners with respect to such treatment are upon submission in accordance with subsection (b) deemed to have been cleared.

(d) SUPPLEMENTAL NOTICES.—

(1) IN GENERAL.—For purposes of subsection (a)(1)(B), supplemental notices under such subsection are in accordance with this subsection if the following conditions are met:

(A) The supplemental notices provide updates of information provided in cleared registrations by providing such information on the effects on patients of the unapproved treatments involved, including information on patient outcomes, as may be available to the qualifying practitioner involved.

(B) The notices are submitted to the Secretary at such intervals as may be specified by the Secretary, subject to paragraph (2).

(2) LIMITATION ON FREQUENCY OF NOTICES; EMERGENCY SITUATIONS.—The Secretary may not require submission of supplemental notices under subsection (a)(1)(B) more frequently than quarterly, except that the Secretary may establish such requirements relating to supplemental notices on emergency situations as the Secretary determines to be appropriate.

(c) CRITERIA.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary shall by regulation issue criteria for carrying out this section.

(2) STANDARD FOR CLEARANCE.—In establishing criteria under paragraph (1) regarding the standard for clearance under subsection (a)(1)(A)(ii), the Secretary is subject to the following:

(A) In the case of an unapproved drug or an unapproved use of a drug, the criteria may not be as stringent as criteria for determining that the drug or use is safe for purposes of section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

(B) In the case of an unapproved device or an unapproved use of a device, the criteria may not be as stringent as criteria under section 513(a) of the Federal Food, Drug, and Cosmetic Act for determining that there is a reasonable assurance of the safety of a device.

(C) The criteria shall provide for the review of any relevant information published in scientific or medical journals.

(D) The criteria may not require as a condition of clearing a treatment that information relevant to the treatment has been published in one or more scientific or medical journals.

(3) CONSIDERATION OF CAPACITY OF PRACTITIONERS.—Criteria under paragraph (1) shall take into account the capacity of qualifying practitioners to comply with the criteria (as compared to the capacity of entities that submit applications under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act), and shall make reasonable efforts to avoid establishing criteria that would present a significant disincentive for such practitioners to develop unapproved treatments.

SEC. 204. UNAPPROVED TREATMENTS; JOHN EISENBERG FORUM FOR FACILITATING EXCHANGE OF INFORMATION IN SCIENTIFIC AND MEDICAL COMMUNITY.

(a) IN GENERAL.—With respect to registrations cleared under section 203 and supplemental notices under such section regarding the registrations, the Secretary, acting through the Commissioner of Food and Drugs, shall (directly or through contract) establish a program in accordance with the following:

(1) The Secretary shall maintain information from the registrations and notices and, subject to subsection (b), make the information available to scientific and medical entities and the general public through establishing one or more Internet sites and posting the information on such site.

(2) The Secretary shall post on the Internet site appropriate comments and information provided in response to the information placed on the site under paragraph (1).

(3) The Secretary shall carry out paragraphs (1) and (2) in a manner reasonably calculated to provide a forum for obtaining and disseminating information, including clinical data, toward the following goals:

(A) Identifying new drugs and devices and uses of such drugs and devices that are reasonable candidates for approval under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act or under section 351 of the Public Health Service Act.

(B) Identifying new drugs and devices and uses of such drugs and devices that constitute a threat to the public health.

(C) Obtaining information for uses with respect to promoting innovations in evidence-based clinical practice and health care technologies under title IX of the Public Health Service Act.

(b) CERTAIN AUTHORITIES.—The posting by the Secretary of information on the Internet site under subsection (a) is subject to the following:

(1) The Secretary shall post the identity and business address of qualifying practitioners with respect to whom registrations under section 203 have been cleared.

(2) In the case of an unapproved drug or an unapproved device made by a qualifying practitioner, the Secretary may not post information sufficient for

others to make the drug or device unless such practitioner has in advance so authorized the Secretary.

(3) The Secretary may impose reasonable restrictions on the format and volume of information to be posted and on the frequency of postings.

(c) CLINICAL GUIDELINES.—

(1) IN GENERAL.—With respect to a registration cleared under section 203, if the Secretary determines that clinical data on the unapproved treatment involved that has been submitted to the Secretary pursuant to such section and this section may be sufficient to demonstrate that the treatment is safe, pure, and potent for purposes of section 351 of the Public Health Service Act (in the case of a biological product), or is safe and effective for purposes of section 505 of the Federal Food, Drug, and Cosmetic Act (in the case of a new drug), or that there may be a reasonable assurance of the safety and effectiveness of the treatment for purposes of section 515 of such Act (in the case of a device), then the Secretary—

(A) shall develop, and publish on the Internet site under subsection (a)(1), clinical guidelines on the treatment; and

(B) shall submit such guidelines to the Commissioner of Food and Drugs.

(2) EFFECT REGARDING APPLICATIONS TO FOOD AND DRUG ADMINISTRATION.—With respect to a biological product for which an application is submitted under section 351 of the Public Health Service Act, or a new drug for which an application is submitted under section 505 of the Federal Food, Drug, and Cosmetic Act, or a device for which an application is submitted under section 515 of such Act, if clinical guidelines under paragraph (1) regarding such product, drug, or device (as the case may be) have been submitted to the Commissioner of Food and Drugs, then the following applies to the application:

(A) If the clinical guidelines are submitted before the application, such Commissioner shall approve or disapprove the application not later than 120 days after the date on which the application is submitted.

(B) If the application is submitted before the clinical guidelines, such Commissioner shall approve or disapprove the application not later than 120 days after the date on which the clinical guidelines are submitted.

(C) If the Commissioner disapproves the application, the Commissioner shall submit to the Secretary, not later than 30 days after the date of the disapproval, a report that provides the reasons underlying the disapproval.

(3) NONCOMPLIANCE OF AGENCY REGARDING TIMEFRAME.—If the Commissioner of Food and Drugs does not within the period of time specified in paragraph (2) approve or disapprove an application to which such paragraph applies, the application is deemed to be approved.

(d) RULE OF CONSTRUCTION REGARDING SUPPLEMENTAL APPLICATIONS; CONSIDERATION OF CLINICAL GUIDELINES.—In the case of a person who holds an approved application under section 351 of the Public Health Service Act or section 505 or 515 of the Federal Food, Drug, and Cosmetic Act, this section may not be construed as having any legal effect with respect to the authority to submit a supplemental application to seek approval of a change for the labeling of the product involved or the indications for use of the product, other than the legal effects of the timeframes under paragraph (2) of subsection (c) and the deeming of approval under paragraph (3) of such subsection, except that—

(1) clinical guidelines under paragraph (1) of such subsection may be considered by the Commissioner of Food and Drugs in reviewing the supplemental application; and

(2) such guidelines may, in the case of a drug with an approved application, be considered by the Commissioner for purposes of section 505A(c) of the Federal Food, Drug, and Cosmetic Act.

(e) CRITERIA.—Not later than one year after the date of the enactment of this Act, the Secretary shall by regulation issue criteria for carrying out this section.

SEC. 205. RELATION TO OTHER LAWS.

(a) CONTROLLED SUBSTANCES ACT.—In the case of a controlled substance, the authority provided pursuant to section 201 for a qualifying practitioner with respect to a drug is subject to the compliance of the practitioner with each provision of the Controlled Substances Act that is applicable with respect to the drug.

(b) STATE LAW.—This title does not supersede any law of a State or political subdivision of a State, including laws governing rights and duties among practitioners and patients.

(c) OTHER PROVISIONS.—This Act does not have any legal effect on any of the following:

(1) Section 561 of the Federal Food, Drug, and Cosmetic Act (relating to expanded access to investigational drugs and devices).

(2) With respect to an unapproved drug or device for which a qualifying practitioner is the original maker, and with respect to an unapproved drug or device made by a manufacturer in a foreign country (in the case of a drug or device to which section 201(b)(4) applies)—

(A) agreements required by such maker as a condition of providing to a qualifying practitioner a supply of the drug or device or instructions for making the drug or device; or

(B) provisions regarding patents or related matters.

SEC. 206. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out the functions under this title of the Commissioner of Food and Drugs (other than providing for Internet sites under section 204(a)(1) or approving an application, disapproving an application, or reporting on a disapproval pursuant to section 204(c)(2)), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2008 through 2012.

(b) INTERNET SITES.—For the purpose of providing for Internet sites under section 204(a)(1), there are authorized to be appropriated $50,000,000 for fiscal year 2008, and such sums as may be necessary for each of the fiscal years 2009 through 2012.

TITLE III—ADDITIONAL FORUMS FOR EXCHANGE OF HEALTH INFORMATION

SEC. 301. JOHN EISENBERG FORUM REGARDING SURGICAL PROCEDURES.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall (directly or through contract) establish a program under which the following occur:

(1) Health care practitioners submit to the Secretary information obtained in the course of their professional practices regarding surgical procedures.

(2) The Secretary maintains the information received under paragraph (1); makes such information available to health care practitioners and the general public through one or more Internet sites; and receives, maintains, and makes available through such site appropriate comments and information provided in response to such information.

(3) The Secretary carries out paragraph (2) in a manner reasonably calculated to provide a forum for obtaining and disseminating information, including clinical data, toward the following goals:

(A) Identifying innovative surgical procedures.

(B) Identifying surgical procedures that constitute a threat to the public health.

(C) Making available to the Secretary information for uses with respect to promoting innovations in evidence-based clinical practice and health care technologies under title IX of the Public Health Service Act.

(b) VOLUNTARY PARTICIPATION.—Subsection (a) may not be construed as requiring that any health care practitioner or other person participate in the program under such subsection.

(c) CERTAIN AUTHORITIES.—The posting by the Secretary of information on an Internet site under subsection (a) is subject to the following:

(1) The Secretary may not post information submitted by a health care practitioner unless the practitioner authorizes the Secretary to include in the posting the identity and the business address of the practitioner.

(2) The Secretary may impose reasonable restrictions on the format and volume of information to be posted and on the frequency of postings.

(d) CRITERIA.—Not later than one year after the date of the enactment of this Act, the Secretary shall by regulation issue criteria for carrying out this section.

SEC. 302. JOHN EISENBERG FORUM REGARDING COMPLEMENTARY AND ALTERNATIVE MEDICINE; DIETARY SUPPLEMENTS AND FOOD.

Section 485D of the Public Health Service Act is amended—

(1) by redesignating subsections (i) and (j) as subsections (j) and (k), respectively; and

(2) by adding after subsection (h) the following subsection:

"(i) JOHN EISENBERG FORUM FOR EXCHANGE OF INFORMATION.—

"(1) IN GENERAL.—The Director of the Center, in consultation with the Commissioner of Food and Drugs, shall (directly or through contract) establish a program under which the following occur:

"(A) Health care practitioners submit to the Director information obtained in the course of their professional practices regarding complementary and alternative treatment, diag-

nostic and prevention modalities, disciplines and systems.

"(B) The Director maintains the information received under subparagraph (A); makes such information available to health care practitioners and the general public through establishing one or more Internet sites; and receives, maintains, and makes available through such site appropriate comments and information provided in response to such information.

"(C) The Director carries out subparagraph (B) in a manner reasonably calculated to provide a forum for obtaining and disseminating information, including clinical data, toward the following goals:

"(i) Identifying alternative treatment, diagnostic and prevention systems, modalities, and disciplines that should be integrated with the practice of conventional medicine as a complement to such medicine and integrated into health care delivery systems in the United States.

"(ii) Identifying any alternative medical practices or procedures that constitute a threat to the public health.

"(iii) Making available to the Commissioner of Food and Drugs information for uses with respect to promoting innovations in evidence-based clinical practice and health care technologies under title IX of the Public Health Service Act.

"(2) DIETARY SUPPLEMENTS AND FOOD.—In consultation with the Commissioner of Food and Drugs, the Director of the Center shall carry out the following:

"(A) Activities under paragraph (1) shall include carrying out such paragraph with respect to information that relates to the effects of dietary supplements and food on diseases and disorders and is obtained by the practitioners in the course of their professional practices and submitted to the Director.

"(B) With respect to paragraph (1)(C) as applied for purposes of this paragraph, the goals shall be the following:

"(i) Identifying dietary supplements and food and uses of such supplements and food that are of clinical benefit in treating particular diseases or disorders.

"(ii) As appropriate, providing for the publication of authoritative statements, within the meaning of section 403(r)(3)(C)(i) of the Federal Food, Drug, and Cosmetic Act, about the relationship between a nutrient and a disease or health-related condition.

"(iii) Carrying out paragraph (1)(C)(iii) with respect to dietary supplements.

"(3) VOLUNTARY PARTICIPATION.—Paragraph (1) may not be construed as requiring that any health care practitioner or other person participate in the program under such paragraph.

"(4) CERTAIN AUTHORITIES.—The posting by the Director of the Center of information on the Internet site under paragraph (1) is subject to the following:

"(A) The Director may not post information submitted by a health care practitioner unless the practitioner authorizes the Director to include in the posting the identity and the business address of the practitioner.

"(B) The Director may impose reasonable restrictions on the format and volume of infor-

mation to be posted and on the frequency of postings.

"(5) CRITERIA.—Not later than one year after the date of the enactment of the Medical Information and Treatment Access Act, the Secretary shall by regulation issue criteria for carrying out this subsection.

"(6) DEFINITIONS.—For purposes of this subsection, the terms 'dietary supplement' and 'food' have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.".

TITLE IV—LEGAL IMMUNITY OF DRUG AND DEVICE COMPANIES

SEC. 401. IMMUNITY FROM LIABILITY.

(a) LOSS ARISING FROM USE OF UNAPPROVED TREATMENTS BY PRACTITIONERS.—

(1) IN GENERAL.—A drug or device company (referred to in this section as a "company") is immune from suit and liability under Federal and State law with respect to all claims for loss arising from the use of a relevant unapproved treatment by a practitioner under a cleared registration under section 203(a).

(2) RELEVANT UNAPPROVED TREATMENT.—For purposes of this section, the term "relevant un-

approved treatment", with respect to a company, means a treatment that uses an approved drug or device that is manufactured by the company, which use—

(A) is an unapproved use that does not involve any changes to the drug or device as manufactured by the company; or

(B) involves changes to the drug or device as manufactured by the company and causes the drug or device to be unapproved.

(3) LOSS.—For purposes of this subsection, the term "loss" means any type of loss, including—

(A) death;

(B) physical, mental, or emotional injury, illness, disability, or condition;

(C) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(D) loss of or damage to property, including business interruption loss.

(4) RULE OF CONSTRUCTION REGARDING USE OF UNAPPROVED TREATMENT.—For purposes of paragraph (1), a practitioner shall be considered to have used a relevant unapproved treatment if the practitioner—

(A) treated himself or herself with the treatment; or

(B) treated a patient with the treatment, whether by administering the treatment to the patient directly or by providing for self-administration by the patient.

(b) PROVISION OF INFORMATION TO PRACTITIONERS UPON REQUEST.—

(1) IN GENERAL.—A company is immune from suit and liability under Federal and State law with respect to any claim arising from the provision by the company of information on a drug or device manufactured by the company in circumstances in which—

(A) the information is provided to a practitioner in response to a request made to the company by the practitioner; and

(B) the information is reasonably believed by the company to be accurate.

(2) RELATION TO CLEARED REGISTRATION.—Paragraph (1) applies without regard to whether the drug or device involved is used as or in a relevant unapproved treatment for which a cleared registration under section 203(a) has been obtained.

(c) OBTAINING INFORMATION FROM PRACTITIONERS.—

(1) IN GENERAL.—In the case of a relevant unapproved treatment for which a cleared registration under section 203(a) is in effect, the immunity under this section for the company involved may not be considered inapplicable on the basis that the company sought or obtained information on the treatment from practitioners or patients, whether through the forum under section 204(a) or otherwise, including circumstances in which the company makes a grant to or enters into a contract with a practitioner for the purpose of obtaining clinical data from the practitioner on the unapproved treatment.

(2) STATUS OF PRACTITIONER AS EMPLOYEE OR AGENT.—In the case of a relevant unapproved treatment for which a cleared registration under section 203(a) is in effect, a practitioner may not be considered to be an employee or agent of the company involved for purposes of section 202(4) solely on the basis that the practitioner is the recipient of a grant or contract referred to in paragraph (1).

TITLE V—GENERAL PROVISIONS

SEC. 501. DEFINITIONS.

For purposes of this Act:

(1) Subject to the definition of the term "drug" established in paragraph (3), the term "approved", with respect to a new drug or a device, means a new drug or a device that is approved or cleared under section 505, 513, or 515 of the Federal Food, Drug, and Cosmetic Act, or under section 351 of the Public Health Service Act.

(2) The terms "device", "label", "labeling", "new drug", and "State" have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.

(3) The term "drug" has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, including provisions added by section 10(a) of the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417; 108 Stat. 4325, 4332) (relating to exceptions providing that dietary supplements, as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act, are not drugs). Such definition applies to paragraph (1) of this section, to section 201(d), to

section 202(3), and to the other provisions of this Act.

(4) The term "drug or device company" means an entity that—

(A) has or has held an approved application for a new drug under section 505 of the Federal Food, Drug, and Cosmetic Act or under section 351 of the Public Health Service Act, or an approved application for a device under section 515 of the Federal Food, Drug, and Cosmetic Act;

(B) is the manufacturer of a device for which a regulation under subsection (d) or (e) of section 513 of the Federal Food, Drug, and Cosmetic Act has been promulgated, or for which an order under subsection (f) of such section has been made;

(C) is the maker of a drug or device that is approved for commercial distribution in a foreign country; or

(D) is a commercial distributor of a drug or a device for an entity specified in subparagraph (A) or (B).

(5) The term "make", with respect to a drug or device, means to manufacture, prepare, propagate, compound, or process the drug or device.

(6) The term "qualifying practitioner" means a practitioner licensed by law to prescribe or administer drugs or devices.

(7) The term "Secretary" means the Secretary of Health and Human Services.

(8) Subject to the definition of the term "drug" established in paragraph (3), the term "unapproved", with respect to a new drug or a device, means that the drug or device is not approved within the meaning of paragraph (1).

(9) The term "unapproved treatment" means treatment with or diagnostic application of an unapproved drug, unapproved device, or unapproved use.

(10) The term "unapproved use", with respect to a new drug or a device, means a use of an approved new drug or a device for a purpose not included in the labeling approved for the drug or device pursuant to the provisions specified in paragraph (1).

SEC. 502. EFFECTIVE DATES.

(a) IN GENERAL.—Subject to subsection (b)—

(1) title II takes effect on the date on which the final rules required under sections 203(e)(1) and 204(e) take effect;

(2) section 301 takes effect on the date on which the final rule required under subsection (d) of such section takes effect; and

(3) the amendment made by section 302 takes effect on the date on which the final rule required under section 485D(i)(5) of the Public Health Service Act (as added by such amendment) takes effect.

(b) ISSUANCE OF CRITERIA.—Sections 203(e)(1), 204(e), and 301(d) of this Act, and section 485D(i)(5) of the Public Health Service Act (as added by section 302 of this Act), take effect on the date of the enactment of this Act.

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